

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte

HANS-MICHAEL EGGENWEILER, ROCHUS JONAS,
MICHAEL WOLF, MICHAEL GASSEN,
and OLIVER POSCHKE

Appeal 2007-2495
Application 10/750,878
Technology Center 1600

Decided: November 27, 2007

Before TONI R. SCHEINER, ERIC GRIMES, and NANCY J. LINCK,
Administrative Patent Judges.

Opinion for the Board filed by *Administrative Patent Judge*
TONI R. SCHEINER.

Opinion Dissenting filed by *Administrative Patent Judge*
NANCY J. LINCK.

SCHEINER, *Administrative Patent Judge.*

DECISION ON APPEAL

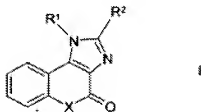
This is an appeal under 35 U.S.C. § 134 from the final rejection of claims 5-8.¹ The Examiner has rejected the claims as lacking enablement. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

DISCUSSION

The present invention is directed to a method of treating various conditions, including autoimmune diseases and tumors, by administering an imidazole derivative which, according to the Specification, “show[s] a specific inhibition of the ‘Rolipram-insensitive’ cAMP phosphodiesterase (PDE VII)” (Spec. 2: 14-16), and an “anti-inflammatory” “antagonistic effect on the production of TNF α (tumour necrosis factor)” (*id.* at 3: 8-9 and 16), and “may also inhibit the growth of tumour cells” (*id.* at 3: 30-31).

Claims 5-8 are on appeal. Independent claim 5 is representative:

5. A method of treating allergic disorders, asthma, chronic bronchitis, atopic dermatitis, psoriasis, inflammatory disorders, autoimmune diseases, osteoporosis, transplant rejection reactions, cachexia, tumor growth, tumor metastases, sepsis, or atherosclerosis comprising administering, to a host in need thereof, an effective amount of a compound of formula I



in which

¹ Claim 9 is also pending, but has been withdrawn from consideration.

R¹ is H, A, benzyl, indan-5-yl, 1,2,3,4-tetrahydronaphthalen-5-yl, dibenzothien-2-yl, or phenyl which is unsubstituted or mono-, di- or trisubstituted by Hal, A, A-CO-NH, benzyloxy, alkoxy, COOH or COOA,

R² is H or A,

X is O or S,

Hal is F, Cl, Br or I,

A is alkyl with 1 to 6 C atoms,

or a physiologically acceptable salt or solvate thereof.

The Examiner rejected the claims under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement, in three separate rejections, each of which covers claims 5-8. The first rejection concerns treatment of tumors, the second rejection concerns treatment of autoimmune disorders, and the third rejection concerns treatment of memory disturbances.

Treatment of Tumors

Claims 5-8 stand rejected under 35 U.S.C. § 112, first paragraph, as lacking enablement. According to the Examiner, the Specification “does not provide sufficient information that all tumors are treatable by the herein claimed compounds described in the methods claimed” (Answer 3).

It is well settled that “a specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented *must* be taken as in compliance with the enabling requirement of the first paragraph of § 112 *unless* there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.” *In re Marzocchi*, 439 F.2d 220, 223 (CCPA

1971) (emphasis in original). “[It] is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement,” *Id.* at 224. In other words, “the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by [the] claim[s] is not adequately enabled by the description of the invention provided in the specification of the application; this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement.” *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993).

Thus, the issue raised by this appeal is *not* whether Appellants have established that the disclosure is enabling for the scope of the claims; the issue is whether the PTO has met its “initial burden of setting forth a reasonable explanation as to why” it is not.

Here, the Examiner’s position is essentially that “[t]he nature of the invention is complex in that it encompasses the treatment of all types of tumors” (Answer 4), “there is no known anticancer agent which is effective against all cancers” (*id.* at 5), and practicing the invention would require “undue, unpredictable experimentation” “for each type of cancer” (*id.* at 7).

On this record, we find that the Examiner has not adequately explained why practicing the invention would have required undue experimentation. First, the Examiner’s reasoning is extremely generalized, and does not begin to address Appellants’ objective statements regarding the inhibitory effects of the subject imidazole derivatives on phosphodiesterase

(PDE) VII (Spec. 2: 11-16), their antagonistic effects on the production of TNF α (Spec. 3: 8-9), or the role of phosphodiesterases and/or TNF α in cancer.

Second, the fact that “there is no known anticancer agent . . . effective against all cancers” is irrelevant. It is true of all known anticancer agents, and neither adds to nor detracts from the enablement of the instant derivatives. Finally, we know of no authority, and the Examiner cites none, that would require Appellants’ imidazole derivatives to be “effective against all cancers” in order to support a claim directed to cancer treatment generally. On the contrary, a claim may encompass inoperative embodiments and still meet the enablement requirement of 35 U.S.C. § 112, first paragraph. *See Atlas Powder Co. v. E.I. Du Pont De Nemours & Co.*, 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984), *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 218 (CCPA 1976), *In re Cook*, 439 F.2d 730, 732, 169 USPQ 298, 300 (CCPA 1971).

In our view, the reasons cited in support of the Examiner’s rejection do not provide a reasonable basis to question the adequacy of the disclosure provided for the claimed invention, and the Examiner’s initial burden has not been met. Accordingly, the rejection of claims 5-8 under 35 U.S.C. § 112, first paragraph, is reversed.

Treatment of Autoimmune Disorders

The Examiner also rejected claims 5-8 under 35 U.S.C. § 112, first paragraph, because the Specification “while being enabling for rheumatoid arthritis, multiple sclerosis, Crohn’s disease, diabetes mellitus, and ulcerative colitis, does not reasonably provide enablement for other autoimmune disorders” (Answer 7).

In this case, the Examiner’s position is essentially that “[t]he nature of the invention is complex in that it encompasses the treatment of all types of autoimmune disorders” (Answer 8), “it is known that some drugs are useful for treating multiple autoimmune diseases, [but] other drugs are not as versatile” (*id.* at 9), and practicing the invention would require “undue experimentation” “for each type of autoimmune disease” (*id.* at 10).

This rejection suffers from the same infirmities as the preceding rejection. Moreover, no explanation is given for distinguishing between “rheumatoid arthritis, multiple sclerosis, Crohn’s disease, diabetes mellitus, and ulcerative colitis,” which the Examiner finds *are* enabled, and “other autoimmune disorders,” which are not. Again, we find the reasons cited in support of the Examiner’s rejection do not provide a reasonable basis to question the adequacy of the disclosure provided for the claimed invention, and the Examiner’s initial burden has not been met. Accordingly, this rejection of claims 5-8 under 35 U.S.C. § 112, first paragraph, is reversed as well.

Treatment of Memory Disturbances

Finally, claims 5-8 stand rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement, because the Specification “does not provide sufficient information that memory disturbances are treatable by the herein claimed compounds described in the methods claimed” (Answer 11).

However, the claims are no longer directed to treatment of memory disturbances. See Appellants’ Amendment filed October 14, 2005. The rejection is reversed.

SUMMARY

We reverse all three of the Examiner’s rejections for lack of enablement under the first paragraph of 35 U.S.C. § 112.

REVERSED

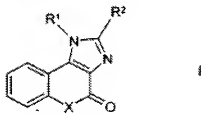
Dissenting Opinion by LINCK, *Administrative Patent Judge*

I respectfully dissent and would affirm the Examiner's § 112 ¶ 1 rejection of all the claims based on lack of enablement. Based on the record before us, particularly given the breadth of the claims and the Specification's limited disclosure, I do not believe Appellants' Specification would have enabled the full scope of their claims.

Claim 5, the only independent claim in the application, recites a method for treating a laundry list of largely unrelated ailments:

allergic disorders, asthma, chronic bronchitis, atopic dermatitis, psoriasis, inflammatory disorders, autoimmune diseases, osteoporosis, transplant rejection reactions, cachexia, tumor growth, tumor metastases, sepsis, or atherosclerosis

with "an effective amount of a compound" from a genus of compounds:



in which R¹ is H, A, benzyl, indan-5-yl, 1,2,3,4-tetrahydronaphthalen-5-yl, dibenzothien-2-yl, or phenyl which is unsubstituted or mono-, di- or trisubstituted by Hal, A, A-CO-NH, benzyloxy, alkoxy, COOH or COOA, R² is H or A, X is O or S, Hal is F, Cl, Br or I, A is alkyl with 1 to 6 C atoms, or a physiologically acceptable salt or solvate thereof.

According to the Specification, these compounds are PDE VII inhibitors, although Appellants do not disclose the level of inhibition for a single compound within their genus (Spec. 2). Rather, the Specification merely discloses how a skilled artisan can determine whether they are inhibitors and, if so, how effective they are. (*See* Spec. 2 (the “affinity of the compounds for . . . (PDE VII) *is* determined by measuring their IC₅₀ values” (emphasis added to show prophetic nature of teaching)).)

More significantly, in my view, Appellants provide very little, if any, evidence their many compounds would be useful in treating all or even a majority of cancers (or any other disease). According to Appellants, “PDE VII inhibitors *may* . . . inhibit the growth of tumour cells and are therefore suitable for tumour therapy.” (Spec. 3.) Support for this suggestion is not based on Appellants’ own work but rather on someone else’s publication regarding a different inhibitor, i.e., PDE IV (Spec. 3). Appellants provide no examples, not even prophetic ones, to guide the skilled artisan how to use their claimed method to treat cancer (or any other disorder). Given Appellants’ lack of meaningful teaching or direction, the Examiner reasonably doubted Appellants’ assertions regarding effectively treating tumors and autoimmune diseases, without limitation (*Answer passim*) and appropriately refused to allow Appellants’ application.

The law is well settled that enablement must be commensurate in scope with the claimed invention. *E.g.*, *Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1379 (Fed. Cir. 2007); *Genentech, Inc. v. Novo Nordisk*, 108 F.3d 1361, 1365 (Fed. Cir. 1997); *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993). A single embodiment *may* be sufficient, *if* that teaching

combined with the knowledge of the skilled artisan would enable the full scope of the claim. *See Johns Hopkins Univ. v. Cellpro Inc.*, 152 F.3d 1342, 1361 (Fed. Cir. 1998). However, in this case, in spite of the breadth of the claims and the well-recognized challenges in treating cancer and autoimmune diseases, *no* embodiment is disclosed.

While I agree with my colleagues that inoperative embodiments do not necessarily defeat patentability (*supra* p. 5 (citing, e.g., *Atlas Powder Co. v. E.I. du Pont De Nemours & Co.*, 750 F.2d 1569, 1576 (Fed. Cir. 1984))), “if the number of inoperative combinations becomes significant, and in effect forces one of ordinary skill in the art to experiment unduly in order to practice the claimed invention, the claims might indeed be invalid.” *Id.* at 1576-77. That’s the problem with this case. Appellants do not disclose a *single* embodiment showing that *any* of the compounds within their genus would be effective to treat *any* type of cancer (or *any* autoimmune disease), even *in vitro*.

The fact that “PDE inhibitors are well known to be implicated in signaling pathways which are instrumental in the formation of tumors” (Reply Br. 5), does not enable the treatment of tumors. Without more, the skilled artisan would not have had a reasonable expectation of success in doing so based on Appellants’ very limited disclosure.

According to Appellants, “the question is . . . whether one of ordinary skill in [the] art could routinely make and test each compound, for a given utility, in order [to] ascertain whether a given compound is operative in the claimed method.” (App. Br. 8.) The problem with Appellants’ statement of the question is that it reflects what they’ve provided—an invitation to

experiment rather than an enabling disclosure. *See Brenner v. Manson*, 383 U.S. 519, 536 (1966) (“a patent is not a hunting license [or] a reward for the search, but compensation for its successful conclusion”), *quoted with approval in Genentech, Inc. v. Novo Nordisk*, 108 F.3d 1361, 1366 (Fed. Cir. 1997).

Under Appellants’ test, if it were routine to test all their compounds in all their claimed treatments and none were found operative, the enablement requirement would still be satisfied. However, that is not the law: Their teachings must enable the full scope of their claims. Thus, although their genus of compounds and uses may include *some* inoperative embodiments, the number that are effective in treating cancer (or autoimmune disease) must bear a reasonable correlation to the scope of the claims. *In re Fisher*, 427 F.2d 833, 839 (CCPA 1970) (“scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art”), *quoted with approval in Invitrogen Corp. v. Clontech Labs, Inc.*, 429 F.3d 1052, 1071 (Fed. Cir. 2005). “While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention.” *Genentech*, 108 F.3d at 1366.

I agree with the majority that the PTO bears the initial burden of “setting forth a reasonable explanation as to why it believes that the scope of protection provided” by the claims “is not adequately enabled by the description . . . provided in the specification” (*supra* p. 4) but do not agree the Examiner has failed to meet that burden, given the scope of Appellants’ claims and their very limited description.

In my view, the Examiner has provided sufficient evidence and reasoned argument to prima facie support her lack of enablement rejection. The Examiner went through each of the *Wands* factors, finding the “nature of the invention is complex . . . exacerbated by the breadth of the claims;” the “guidance given by the specification . . . is limited,” disclosing only that “‘PDE VII inhibitors *may* also inhibit the growth of tumor cells;” there is no working examples; “there is no known anticancer agent which is effective against all cancers” (citing Carter et al., *Chemotherapy of Cancer* (2nd ed. 1981)); “the existence of . . . a ‘silver bullet’ is contrary to our present understanding in oncology” because “cancers arise from a wide variety of sources;” “it is beyond the skill of oncologists today to get an agent to be effective against cancers generally;” “[c]ancers are especially unpredictable due to their complex nature;” and “it would require undue, unpredictable experimentation to practice the claimed invention” (Answer 3-7.) These findings are consistent with what the skilled artisan in the pharmaceutical field would have known at the time this application was filed (or even today).

Given the Examiner’s reasonable explanation why she doubted Appellants’ claims were enabled, it was up to Appellants to rebut her evidence. Given the record before us, I find they did not do so convincingly. While they argue the Carter reference “appear[s] to suggest that some drugs do not ‘interact’ with tumors located in the various areas listed” but does not explain “this ‘interaction’ and whether its significance translates to therapeutic modalities” (Reply Br. 6). In my view, Appellants’ argument further supports the Examiner’s position: The skilled artisan would have

recognized that, even though a drug interacts with a tumor, it may not be effective in treating the tumor. To the extent Appellants are suggesting that a drug, without any interaction with the tumor, would be expected to provide effective treatment, I disagree, finding Appellants provided no evidence supporting such an argument.

Appellants' limited disclosure, i.e., their "contribution," is not commensurate in scope with the broad claims they seek. Thus, they should not be granted a patent that would exclude others from practicing the claimed invention for a substantial period of time.

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MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
2200 CLARENDON BLVD.
SUITE 1400
ARLINGTON, VA 22201